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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,523

03/30/2006

Orest Olejnik

17630(AP)

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51957 7590 09/16/2008  
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EXAMINER

HAVLIN, ROBERT H

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

09/16/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/574,523	<b>Applicant(s)</b> OLEJNIK ET AL.	
	<b>Examiner</b> ROBERT HAVLIN	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9 and 14-17 is/are rejected.
- 7) ☒ Claim(s) 10-13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/9/06</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

**Status of the claims:** Claims 1-6, 9-17 are currently pending.

**Priority:** This application is a 371 of PCT/US04/27914 (08/26/2004) which claims benefit of 60/509,955 (10/08/2003).

**IDS:** The IDS dated 5/9/06 was considered.

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I in the reply filed on 7/14/08 is acknowledged. The traversal is on the ground(s) that the technical feature linking the claims is a contribution over the prior art. This is not found persuasive because the reference cited in the prior office action and the following rejection detail how the technical feature is not a contribution over the prior art.

The requirement is still deemed proper and is therefore made FINAL.

Applicant also elected the species of brimonidine and TFF1 (reading on all of the claims).

Because the generic claim was not found patentable, the claims are restricted to the elected species only and the remaining subject matter held withdrawn.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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3. Claims 1-6, 9 and 14-17 are rejected under 35 U.S.C. 102(a) and (e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Podolsky (US 2003/0185838).

The instant claims are for a composition comprising an alpha-2-adrenergic agonist and a trefoil factor peptide at various dosages and forms.

Podolsky teaches methods and compositions for treating lesions of the respiratory epithelium. Specifically, the reference teaches and claims compositions comprised of trefoil factor peptides combined with second therapeutic agents including epinephrine.

At the relevant part, the reference teaches the following:

[0061] Bronchodilator Agents

[0062] Any active bronchodilator agent may be co-formulated with the trefoil peptide in the usual doses for respiratory application to the nasal-pharyngeal or tracheo-bronchial anatomy. Useful bronchodilators include, but are not limited to methylxanthines (e.g., theophylline, theobromine, and caffeine), sympathomimetic agents (e.g., adrenaline, epinephrine, isoproterenol, and beta -adrenergic agonists), cholinergic receptor antagonists such as ipratropium bromide and tiotropium and neurokinin receptor antagonists.

Thus, the reference teaches formulations of a trefoil peptide with an alpha-2-adrenergic agonist because, for example, epinephrine is known as an alpha-2-adrenergic agonist (See PubMed abstract of: Cell Regul. 1990 May;1(6):445-51). Thus the prior art anticipates the claims.

In the alternative, the claims would be obvious to one of ordinary skill in the art because the prior art teaches the combination of the two elements (from a finite number of alternatives) and the reference teaches several different formulations which

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through routine optimization would lead one of ordinary skill in the art to the instant invention.

### ***Claim Objections***

The pending claims are objected for reading on non-elected subject matter as a result of the restriction to the elected species ONLY.

### ***Conclusion***

The claims are not in condition for allowance.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Havlin whose telephone number is (571) 272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/  
Robert Havlin, Ph.D.  
Examiner  
Art Unit 1626

/Kamal A Saeed, Ph.D./  
Primary Examiner, Art Unit 1626